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Published in:
Disability and Rehabilitation

DOI:
[10.3109/09638288.2010.510177](https://doi.org/10.3109/09638288.2010.510177)

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Document Version
Publisher's PDF, also known as Version of record

Publication date:
2011

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Van Abbema, R., Van Wilgen, C. P., Van der Schans, C. P., & Van Ittersum, M. W. (2011). Patients with more severe symptoms benefit the most from an intensive multimodal programme in patients with fibromyalgia. *Disability and Rehabilitation*, 33(9), 743-750. <https://doi.org/10.3109/09638288.2010.510177>

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RESEARCH PAPER

Patients with more severe symptoms benefit the most from an intensive multimodal programme in patients with fibromyalgia

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Accepted July 2010

Abstract

Purpose. Patients with fibromyalgia (FM) experience symptoms over a long period of time impacting their quality of life (QoL). Patients are often treated in multimodal programmes that combine physical and cognitive treatment modalities. Purpose of this study was to identify prognostic factors of effectiveness of a multimodal programme.

Method. A prospective study was performed with a group of 87 patients with FM who had participated in a multimodal programme. The Revised Illness Perception Questionnaire (IPQ) and the Fibromyalgia Impact Questionnaire (FIQ) were used. Criterion for clinically relevant improvement was a decline in total FIQ score of 12.5 points or more after the treatment programme. Investigated determinants of improvement of QoL were patient characteristics, illness perceptions (IP) and QoL at baseline.

Results. QoL of 34 patients with FM made a clinically relevant improvement after the programme. There was no difference in age, number of years with pain, number of years diagnosed or IP compared to the group that did not improve. The group of patients with an improved QoL after the programme reported severe impact on daily living, highest intensity of pain and most depression at baseline.

Conclusions. Total FIQ score on QoL, intensity of pain, morning tiredness and depression can be used as prognostic factors to pre-select patients with FM for a multimodal treatment. IP were not adequate to predict treatment outcome. An intensive multimodal programme seemed most suitable for patients with severe symptoms and limitations.

Keywords: Fibromyalgia, prognostic factors, multimodal programme, illness perceptions, quality of life

Introduction

Fibromyalgia (FM) is a complex syndrome with chronic widespread pain as a defining feature. Other symptoms frequently reported include: sleep disturbance, irritable bowel, headache, excessive fatigue and mood disorders [1]. FM is associated with significant impairments on quality of life (QoL) and function. The prevalence rates in western countries vary from 2 to 3% and the syndrome affects mostly women [2]. As with other pain syndromes the aetiology appears to have physical, psychological,

behavioural, cognitive and environmental features in patients with FM but the specific aetiology of FM is still not completely understood [3–5]. Chronic pain, such as in patients with FM, is the most common cause of long-term disability and of high direct and indirect costs to modern society [6].

There is a large diversity in treatments for FM. Management of the different features of FM is often combined in a multimodal programme. Lemstra and Olszynski (2005) assessed the effectiveness of a 6-week during multidisciplinary rehabilitation programme. They found significant changes in health

status, average pain intensity, pain-related disability, depressed mood, days in pain and hours in pain after the intervention. At 15 months follow-up, all health outcomes retained their significance except health status [7]. A community patient education and exercise programme, using a cognitive behavioural approach for people with FM, reported short-term effects on function and symptoms measured with the FIQ and self-efficacy measured with the Arthritis Self-efficacy scale. These improvements did not sustain at the 8-month follow-up [8].

Meta-analysis shows that multimodal programmes have beneficial short-term effects on key-symptoms of FM such as pain, fatigue and depressed mood and improve self-efficacy and physical fitness [9]. Some positive effects were detected at follow-up (after 3–4 months) for physical fitness and self-efficacy. However, these positive effects declined with time (after 6–12 months) [9]. In general, the effects found are rather small and the percentage of patients showing significant clinical improvement is minimal [9–11]. It is not clear which specific treatment components are effective and which patients benefit from which treatment components [12]. Patients with FM are a heterogeneous group with the subgroups being identified based on their disease mechanisms (immunologic profile) [13], physical signs (quantitative sensory testing) [14], psychological measures (pain cognitions) [15] or a combination (pressure-pain thresholds and mood and cognition) [16].

In the present article, we focus on psychological measures and disability of the heterogeneous group of patients with FM. Level of disability and QoL of chronic pain patients can be predicted based on patient specific characteristics, such as pain intensity, cognitions and illness perceptions (IP). The modifying effects of IP on the association between impairments in body structures and functions due to osteoarthritis (OA) and limitation in activities in the lower extremities were investigated in a study in patients with OA [17]. Patients who strongly believed that OA had a major impact on their functioning and who strongly believed in the likely chronic duration of their OA also had an increased risk to report more limitations than expected from clinical and radiological assessments. IP also have been described as prognostic factors for determining prognosis in patients with low back pain [18]. Patients with low back pain who expected their back problem to last a long time, who perceived serious consequences on their daily lives and who held weak beliefs about the controllability of their back problem were more likely to have poor clinical outcomes after 6 months. Cognitions like fear-avoidance beliefs, catastrophising and specific IP have been identified as important patient specific characteristics and proven

to be better predictors of disability and QoL than pain itself [19–22]. IP are beliefs that patients hold about diseases. IP were first described by Leventhal et al. in the Common Sense Model (CSM) [23]. According to this model, patients develop a cognitive representation that is used to make sense of their illness experience. Research has suggested that IP have common content and can be ordered in five dimensions: identity, causes, consequences, time line and cure-control [24]. IP are thought to determine coping strategies and emotional responses to the disease and are important in directing the recovery process [23].

Research on prognostic factors for treatment success in chronic pain syndromes have been studied extensively in chronic low back pain (CLBP). Highly distressed patients with strong feelings of disability, who see their pain as an uncontrollable and highly negative life event, derive less benefit from treatment than other patients. Decreased negative emotional responses to pain, decreased perceptions of disability, and increased orientation toward self-management during the course of treatment predict favourable treatment outcome [25]. In another study, Health Locus of Control belief was associated with a successful treatment outcome in patients with CLBP. Those patients with stronger internal beliefs had gained more from the treatment, learned their exercises better and had higher exercise compliance during the follow-up period. Symptoms of psychological distress were significantly associated with poorer accomplishments of the back exercises [26].

A study with patients with CLBP in an outpatient university based pain rehabilitation setting analysed the relationship between self-reported psychological factors (psychological distress, depression, self-efficacy, self-esteem, fear of movement, pain cognitions and coping reactions) and disability measured with both performance tests and self-reports. This study could not confirm strong relationships between these two sets of variables [27]. Another CLBP study showed that high scores of pain intensity, depression and fear-avoidance beliefs may contribute to the prediction of improvement after a rehabilitation programme for patients with CLBP [28].

Little is known about prognostic factors for positive response to multimodal treatment programmes for patients with FM. The aim of the present study is to identify prognostic factors of effectiveness for patients with FM participating in a multimodal programme. In this study we explored patient characteristics, IP and QoL of patients with FM as possible predictors of treatment outcome. Because negative cognitions are an important predictor of disability, we expect that patients with negative IP's will have a worse treatment outcome.

Methods

Design

A prospective treatment study was performed; patients were evaluated at baseline and post-treatment (pre-post design) to determine if patient characteristics (age, duration of pain, years diagnosed with FM), IP or initial scores on QoL were predictors to success of the programme. The study outline is presented in Figure 1.

Multimodal treatment programme

The multidisciplinary programme active living with Fibromyalgia (MPF) combined self-management, education and physical therapy [29]. The

programme comprised an educational part of seven sessions and a physical therapy part of 25 sessions (Figure 2). The educational part was aiming at: cognitive restructuring, information on FM, goal-setting, pacing, distraction and assertiveness training. The goal of cognitive restructuring was changing inadequate cognitions by educating patients about pain mechanisms in FM and about the importance of an active lifestyle. Self-management was promoted by setting goals, pacing, distraction techniques and assertiveness training.

The 25 sessions of physical therapy were aiming at: behavioural changes using a graded activity programme, relaxation and goal setting. The exercises were performed according to the operant conditioning principles using a graded activity programme to achieve behavioural change. Total duration of the MPF programme was 17 weeks.

Study population

Patients were referred to the MPF programme by their general practitioner or by a medical specialist. They met the inclusion criteria considered by a nurse specialist. Inclusion criteria were a diagnosis of FM by a GP or rheumatologist, the patient demands no further medical assessment, agrees with the purposes of the programme, is mentally and physically able to follow the programme and is motivated. Exclusion criteria comprise the patient has already followed a similar programme or is undergoing treatment elsewhere at the moment. The patient were furthermore excluded when having cognitive disorders,

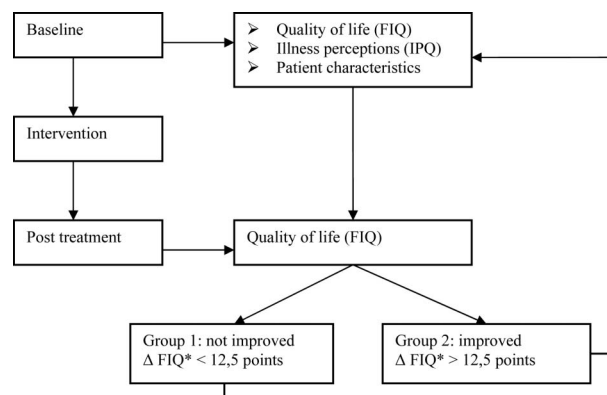


Figure 1. Study outline. *ΔFIQ = 'Total FIQ score' at post treatment minus 'total FIQ score' at baseline.

Education	Week	Physical therapy programme (PT)
What is fibromyalgia Personal targets education	1	
Communication	2	
Fibromyalgia and emotion	3	
Fibromyalgia and stress	4	PT session 1 Introduction, purpose of the programme, what is fibromyalgia, information about chronic pain, education about staying active, graded activity principles, personal targets after the programme, information about the partner day
	5	PT session 2,3 Relaxation (Jacobsen, Mitchell) getting familiar with the training appliances, hand out personal training file to registration achievements
I, others and the environment	6,7	PT session 4,5,6 Relaxation Start exercises
How to say what I mean	8,9	PT session 7,8,9 Exercises
How to proceed.....?	10	PT session 10 Exercises
	11-17	PT sessions 11-24 Exercises, two personal evaluation sessions, partner day

Figure 2. Multidisciplinary programme active living with fibromyalgia (MPF).

psychopathology, acute psychosocial problems, insurance claims or medical re-assessment, pain as a consequence of malignancy, extreme fatigue, not able to understand or speak Dutch or to function in a group. Patients signed an informed consent form before entering the study. Included patients were clustered in a group of 8–12 patients for the educational part; this group was later divided into two separate groups for the physical therapy part.

Twenty physical therapy practices in the northern provinces of the Netherlands implemented the MPF programme. The physical therapists were responsible for the treatment process and evaluation measurements. Only questionnaires that were complete at baseline and post treatment were included in the analyses.

Questionnaires

Two questionnaires were used in this study; the Fibromyalgia Impact Questionnaire (FIQ) and the Revised Illness Perception Questionnaire (IPQ-R).

FIQ

QoL was evaluated with the FIQ. The FIQ measures the impact of FM on patients' lives, in terms of symptoms and limitations. Overall it has credible construct validity, reliable test-retest characteristics and a good sensitivity in demonstrating therapeutic change [27,28]. The FIQ was found to be the most efficient instrument for discriminating and assessing the impact of FM on QoL [30,31].

The FIQ is composed of 10 items. Patients were asked to rate their status within the last week. The first item includes 10 questions concerning physical functioning, rated on a 4-point Likert type scale. Items 2 and 3 report the number of days feeling good (range 0–7) and number of days unable to work (range 0–7). Item 4 through 10 are horizontal linear scales where the patient rates; difficulty in doing their job, level of pain, fatigue, morning tiredness, stiffness, anxiety and depression (range 0–10).

Item 1–3 are normalised to 10 points. Total score of the FIQ ranges from 0 to 100 points. The higher the score, the more functional impairment and symptoms are experienced. In this study, total FIQ score was calculated by leaving item 3 out, because most patients were unemployed.

IPQ-R-Dlv

The IPQ-R provides a psychometrically acceptable quantitative assessment of the key components of

patients' perceptions of illness [24]. The IPQ-R English language version was shown to give good internal reliability of the domains, good short and longer-term retest reliability and sound discriminant validity, known group and predictive validity in a study population consisting of patients with a variety of diseases (asthma, diabetes, rheumatoid arthritis, acute pain, chronic pain, myocardial infarction, multiple sclerosis (all from Auckland, New Zealand) and HIV (from Brighton, United Kingdom) [24]. The English language version for rheumatoid arthritis and the Dutch version for diabetes were used as examples [www.uib.no/ipq] to construct the Dutch language version for FM. The terminology 'my illness' was changed into 'my fibromyalgia'. The Dutch language version of the IPQ-R has acceptable psychometric properties [32].

The IPQ-R Dlv consists of nine domains. In the first domain 'illness identity', patients are asked if they experience a specific symptom (based on a total of 14 possible symptoms) and whether they believe this symptom is related to FM. The score on the identity domain is calculated of the sum of the yes-rated items related to FM.

The following seven domains of the IPQ-R Dlv are scored on a 5-point Likert type scale (1–5): strongly disagree, disagree, agree nor disagree, agree and strongly agree. These domains include timeline acute/chronic (perceptions of likely chronic duration of the health problems); timeline cyclical (perceptions of likely variability of the health problems over time); consequences (beliefs about illness severity and impact on physical, social and psychological functioning); personal control (belief in personal control over the illness); treatment control (belief in cure through treatment); illness coherence (comprehension or understanding of the illness); and emotional representations (perception of negative emotions generated by the illness).

High scores on the identity, timeline, consequences and cyclical domains represent a negative view of the illness. High scores on the personal control, treatment control and coherence domains represent positive beliefs about the controllability of the illness and a personal understanding of the condition. Finally, the causal domain is presented as a separate section. It consists of 18 attribution items, which are scored on the same Likert type scale. The causal domain can be divided into four sub domains: psychological attributions, risk factors, immunity and accident or chance.

Data analysis

Data were analysed using SPSS 15.0. We divided the population into two groups based on clinical

outcome. A decrease in total FIQ score after the programme means improvement in QoL. When FIQ score was at least 12.5 points lower after the programme compared to baseline, that difference was considered as clinically relevant. This cut-off point was based on the mean of within group changes of 17 clinical intervention studies all using the total FIQ score as outcome parameter [33].

Age, the FIQ scores and scores on the IPQ dimensions at baseline of the two groups were compared using an independent sample *t*-test. Number of years with pain and number of years diagnosed were not normally distributed and therefore analysed with a Mann-Whitney test.

When the FIQ had more than three missing values or the IPQ had more than five missing values or these missing values were not randomly distributed, the questionnaires were excluded from this study. The remaining missing responses were imputed using the sample median.

Results

In total, 87 patients randomly selected in 20 different physiotherapy practices completed the IPQ at baseline and the FIQ at baseline and post-treatment. There were 42 participants who did not complete all questionnaires until post-measurement. The missing responses of the remaining 87 questionnaires were imputed with the sample median. For IPQ at baseline 1.7% of the answers was imputed with the sample median. For the FIQ, 1.9% of the answers was imputed at baseline and 4.4% was imputed after the programme with the sample median.

Nine men and 78 women participated in the study, which is consistent with population characteristics of patients with FM. Mean age was 46 (SD12) years, mean years with pain was 13 (SD 11) and the patients were diagnosed with FM with a mean duration of 3 (SD 5) years. The patient population was divided in two groups based on clinical outcome. Thirty-four patients improved in QoL because of a decrease in total FIQ score of 12.5 points or more. Fifty-three patients improved less than 12.5 points or did not improve at all. An improvement of less than 12.5 points was not considered clinically relevant. Therefore, all 53 patients were gathered in the group that did not improve on QoL.

The two groups were compared at baseline on age, years of pain, years diagnosed, IPQ scores and FIQ scores, to analyse possible predictors of outcome (Table I). Group 1 is the group who did not improve their QoL; Group 2 did improve after the programme. The mean age of the groups was comparable. Years of pain were higher and number of years diagnosed lower in Group 2 but these differences

were not significant. The total FIQ score at baseline was significantly higher in Group 2. Group 2 scores on the FIQ dimensions were generally higher post treatment, but only pain intensity, morning tiredness and depression scores differed significantly compared to before the programme. There were no significant differences in baseline scores between the two groups on the IPQ dimensions.

Discussion

The primary goal for this prospective non-controlled treatment study was to identify prognostic factors for patients with FM who benefit from a multimodal programme. We expected IP to be a prognostic factor, because negative IP have proven to be a predictor of disability. This hypothesis could not be confirmed in our study. Neither patient characteristics like age, number of years with pain and number of years diagnosed with FM were of predictive value. There was, however a significant difference between the two groups on their baseline scores of the FIQ. 'Pain intensity', 'morning tiredness', 'depressed mood' and total FIQ score were significantly higher at baseline for the group that improved the most in QoL after the programme. These results imply that a multimodal programme could specially benefit patients that have more severe problems prior to the programme.

In a study with patients with CLBP, high scores of pain intensity, depression and fear-avoidance beliefs may contribute to the prediction of improvement after a rehabilitation programme [28]. This is in line with our finding of high scores of pain intensity and depression before the programme in patients with FM that report the most improvement after the programme.

In several studies IP have been associated with perceived limitations, disability and well-being [17–23]. Patients with low back pain with negative IP were more likely to have poor clinical outcome after 6 months [18]. However, a study with patients with CLBP in a outpatient university based pain rehabilitation setting analysing the relationship between psychological factors (psychological distress, depression, self-efficacy, self-esteem, fear of movement, pain cognitions and coping reactions) and performance based and self-reported disability, could not confirm a strong relationship [27].

In our study IP had no predictive value for effectiveness of a multimodal programme. The IP of our study population were comparable to FM populations in other studies; patients perceiving FM to be chronic with serious consequences and perceiving little personal control and little treatment control [21,34]. However the IPQ-R Dlv we used

Table I. Between group comparison of predictor variables at baseline.

	Not improved Group 1 (N = 53) Mean (SD)	Improved Group 2* (N = 34) Mean (SD)	Between group comparison P value
<i>Patient characteristics</i>			
Age	45.3 (12.7)	45.8 (10.7)	0.87
Number of years with pain	12.8 (9.4)	13.4 (13.0)	0.90
Number of years diagnosed	3.7 (5.9)	2.7 (3.7)	0.33
<i>Quality of life (FIQ)</i>			
Physical functioning norm. score	6.4 (1.9)	6.2 (2.1)	0.61
Days feel good norm. score	6.1 (2.9)	6.1 (2.5)	0.98
Influence pain on work	6.8 (2.5)	7.6 (2.2)	0.15
Pain intensity	6.7 (1.9)	7.5 (1.7)	0.05*
Fatigue	7.4 (2.5)	8.0 (1.6)	0.17
Morning tiredness	7.1 (2.4)	8.4 (1.3)	0.01**
Stiffness	7.3 (2.2)	7.8 (1.7)	0.21
Depressed	4.0 (2.6)	5.5 (2.4)	0.01**
Anxiety	5.4 (2.9)	6.5 (2.4)	0.07
Total FIQ (- fiq3)	63.6 (14.5)	70.6 (10.7)	0.01**
<i>Illness perceptions (IPQ)</i>			
Identity (0–14)	5.8 (2.2)	6.4 (2.2)	0.13
Timeline (6–30)	25.1 (3.8)	25.6 (3.5)	0.50
Timeline cyclical (4–20)	14.5 (3.3)	15.6 (2.6)	0.11
Consequences (6–30)	19.7 (4.0)	19.8 (4.9)	0.84
Personal control (6–30)	21.5 (3.8)	22.6 (3.6)	0.21
Treatment control (5–25)	17.4 (3.3)	16.7 (3.4)	0.37
Illness coherence (5–25)	12.9 (2.3)	12.8 (2.2)	0.76
Emotional report (6–30)	15.9 (4.2)	17.4 (5.5)	0.15
<i>Attribution</i>			
Psychological attribution (6–30)	17.9 (5.3)	18.8 (4.9)	0.43
Risk factors (7–35)	14.8 (3.9)	15.5 (3.9)	0.43
Immunity (3–15)	6.3 (2.1)	6.7 (2.2)	0.50
Accident or chance (2–10)	5.4 (1.6)	4.8 (1.6)	0.11

* $p < 0.05$; ** $p < 0.01$.

was possibly not specific enough for the perceptions patients with FM have. The IPQ-R is not a disease specific questionnaire. We replaced the words 'my illness' by the words 'my fibromyalgia'. The authors of the IPQ-R encourage researchers to make the IPQ-R more disease specific by adding new items [24]. Addition of FM specific items such as 'FM is caused by a rheumatic disease', could have made the questionnaire more sensitive. The current study has some limitations to consider. 'There are some possible confounders (current level of activity, medication, employment status) that were not taken into analysis because of lack of this information. We suggest that these factors will be included in future research'. Possibly, a type II error occurred by a floor effect in FIQ scores. Because of the chronic nature of FM most patients will remain to experience FM symptoms, meaning that FIQ scores will remain relatively high. The purpose of the multimodal programme is not to cure FM, but learning to cope with FM. A study establishing norm scores for the FIQ for patients with FM described an average score of 57 points (or 63 when unemployed) [35]. Patients that have higher FIQ scores at baseline are more

likely to decrease their scores and improve after the programme.

Patient selection bias could be caused by the fact that physical therapists working in the 20 practices that implemented the MPF programme were responsible for collecting and sending the questionnaires. The selection of patients is therefore at random and only completed questionnaires at baseline and post treatment were used in this study. Unfortunately, we had to exclude 42 participants from our results who did not complete all questionnaires until post-measurement.

This study was a first attempt to identify factors of success at a multimodal treatment programme for patients with FM. We explored the possibility to look at present patient characteristics and symptoms before attending a treatment programme. This is an important issue for further exploration because matching specific patient characteristics to specific treatment modalities could improve effectiveness of treatment and could lower health costs.

Cognitions have proven to be important in predicting disability and QoL. Therefore, cognitions of patients should always be taken into consideration

in multimodal programmes for patients with FM. Based on this study, IP did not seem valid to preselect patients that benefit from intensive multimodal programmes. We think IP measured with the IPQ-R Dlv were too generic to identify patient subgroups and relate this to treatment outcome. Measuring and investigating prognostic factors like cognitions in future FM research and clinical treatment should possibly focus on more specific cognitions like pain catastrophising, somatisation, acceptance of pain, kinesiophobia or fear avoidance beliefs.

The results showed it could be clinically relevant to consider the severity of symptoms and limitations before a multimodal treatment programme and prescribe intensive multimodal programmes to patients with the lowest QoL. In patients with FM with less severe symptoms and limitations it could be more effective if only those specific treatment modalities are selected that provide for their specific needs. These treatment modalities could be self-management aspects (acceptance, goal-setting), physical fitness, relaxation, restructuring specific cognitions or a combination of these treatment modalities. The selection of treatment modalities for specific subgroups of patients with FM can be an important step in lowering health costs.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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